Patent Application

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Alejandro Dee, et al.	Date:	
Date Filed:	February 20, 1996	Docket No.:	BABSBRO-7
App. No.:	08/602,498	Art Unit:	1617
For:	FATTY ACID ANTIMICROBIAL	Examiner:	M. MOEZIE

DECLARATION OF MICHAEL H. GARDNER, D.V.M.

I, Michael H. Gardner, D.V.M., hereby declare as follows:

1. I am a licensed veterinarian and the owner of Northside Veterinary Clinic in Mountain Grove, Missouri.

2. In early 1993, I approached Babson Bros. Co. ("Babson") with the general concept of a winterizing and conditioning teat dip.

3. Babson agreed that such a product would be marketable, and proceeded with development.

4. I assisted with the development of the product, including conducting field tests.

5. Early in the development of the product, it contained butyl hydroxy anisol ("BHA") as the germicidal agent. By May, 1994, this product, referred to as DX-206, had been tested by Babson

scientists in laboratory conditions, but was found to be less effective in those tests than currently available teat dips.

6. Based on these results, a fatty acid mixture was added to DX-206 as an additional germicide.

7. By December 6, 1994, the BHA had been removed from the DX-206 formulation.

8. Although DX-206 had performed well in laboratory tests, such performance was not indicative of how the product would perform in the field, under extreme conditions and with actual dairy animals.

9. To commence this field testing, on January 31, 1995, Babson sold me an amount of DX-206 in various sized containers. I then sold varying amounts of DX-206 to my herd health clients, asking them to try the product for test purposes. My herd health clients are those that I visit on a regular basis, usually once per month. I provided DX-206 to approximately 36 of my clients, from February 1, 1995 to April 13, 1995. Of these 36 clients, I sold DX-206 to only thirteen of them prior to February 20, 1995.

10. I sold the product to these clients because in my experience. If a test product is provided to the dairyman at no cost, or at a substantially reduced cost compared to the product the dairyman is currently using, the dairyman will have a tendency to overstate the effectiveness of the test product in an effort to obtain a lower cost or free test product. If the test product is provided at a price or is substantially near the projected retail price, an unbiased evaluation of the product from the dairyman is usually obtained. In this instance, DX-206 was sold at a price less than the eventual retail price;

however, this price was greater than that for the teat dips that my clients were currently using. As a result, I knew that the results I received from those testing DX-206 would be reliable.

11. Some of my herd health clients that I wanted to field test DX-206 were located in an area serviced by Lonnie Anderson for Babson. For those clients, I suggested that Babson sell the DX-206 to Mr. Anderson for resale to my clients for the field test.

12. After Mr. Anderson and/or I provided DX-206 to my herd health clients, I regularly monitored the efficacy of DX-206 via personal visits and phone conversations to these clients over at least a period of several months. I then reported any problems to Babson.

13. For example, I sold Wendell Webb five gallons of DX-206 on February 3, 1995. On one of my visits to check how DX-206 was performing, the Webbs reported that DX-206 appeared to be irritating to the skin of their animals. I provided a sample the Webb's DX-206 to Babson in April, 1995, to ascertain any possible chemical reaction that could cause the irritation. On May 2, 1995, Babson's Dr. Charles Gradle responded that he could not find the reason for the irritation.

14. Further, at the time I was conducting field tests of DX-206, protocol testing using control animals to determine the efficacy of DX-206 in a more quantitative way had not yet begun. Those tests, which were conducted at Cornell University, did not begin until the late spring/early summer of 1995, and were on-going as of July, 1995.

15. Moreover, changes were made to DX-206 based on feedback I received during my field testing. For example, in October 1995, based on complaints from some of my clients that DX-206 did not work well in teat dip sprayers, more water was added to the formulation to make the product easier to spray. Wintergreen was also added at this time to improve the odor of the product.

16. Before DX-206 was field tested by certain of my clients under my supervision, I did not know whether it would work for its intended purpose. In fact, although many of my clients were quite satisfied with the DX-206 formulation, others, including the Webbs decided not to use DX-206 based on their experience in the field test. For example, three of the first four clients who used DX-206 on their herds in the field test no longer use the product, because of one or more problems with the product in this development period.

17. Due to my contributions to the development of Dermasept, I receive a royalty from Babson based on sales of Dermasept. The agreement by which I receive these royalties was not signed by Babson and received by me until August 10, 1995.

18. DX-206 was not approved for sale under the name Dermasept™ until May 1996.

19. In summary, in my opinion, the early sales by me or by Mr. Anderson on my behalf of DX-206 to my herd health clients were for testing purposes in the early development period of the product. Until I began to see positive results from the use of DX-206 in actual herds by my clients, I did not know whether DX-206 would have satisfactory efficacy against mastitis in harsh, real world conditions; or whether it would have the teat conditioning properties I hoped it would.

I do hereby certify that the foregoing is true and correct under penalties of perjury under the laws of the United States of America.

Date: 9/14/99

Michael H. Gardner, D.V.M.